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VIA ELECTRONIC FILING

The Honorable Leonard P. Stark
United States District Court
For the District of Delaware
822 North King Street
Wilmington, DE 19801

Re: *Avanir Pharms., Inc., et al. v. Actavis South Atlantic LLC, et al.*
C.A. No. 11-704 (LPS) (Consolidated) (D. Del.)

Dear Judge Stark:

This firm, together with Quinn Emanuel Urquhart & Sullivan LLP, writes on behalf of Plaintiffs in response to Your Honor's February 25, 2014 Order requesting supplemental briefing on the Federal Circuit's decision in *Galderma Labs. L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013). D.I. 475. The Federal Circuit's decision does not change any of the legal standards that Plaintiffs rely upon, and for all of the reasons set forth in Plaintiffs' post-trial briefing, the claimed inventions remain non-obvious. The Federal Circuit reversed in *Galderma* based on the specific fact pattern in that case. While Plaintiffs disagree with the Federal Circuit's application of the law to the facts in *Galderma*, a similar fact pattern is not present in this action. Indeed, Defendants themselves previously argued that the facts of *Galderma* are "inapposite to the present case." D.I. 450 at 13-14. Accordingly, the Federal Circuit's opinion confirms that, under the proper legal standards, Defendants have failed to meet their burden of proving any asserted claims of U.S. Patent Nos. 7,659,282 and 8,227,484 ("the '282 and '484 patents") obvious by clear and convincing evidence.

I. *GALDERMA* DOES NOT AND CANNOT MAKE NEW LAW

Galderma does not change the law under which Defendants have failed to set forth a *prima facie* case of obviousness.[1] Specifically, Defendants have failed to: (1) identify a recognized

[1] A Federal Circuit panel decision cannot make new law. *See Sacco v. DOJ*, 317 F.3d 1384, 1386 (Fed. Cir. 2003) ("A panel of this court is bound by prior precedential decisions unless and until overturned en banc."). Moreover, any direct conflict between two panel decisions of the Federal Circuit is resolved in favor of the earlier decision. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988). Thus, the decision in *Galderma* is at most cumulative to the extensive precedent already cited in post-trial briefing.

problem to be solved; (2) prove that there was a motivation to arrive at the claimed DM and Q doses in the claimed ratios; and (3) prove that a POSA would have had a reasonable expectation that the claimed doses and ratios would be successful in treating PBA. As set forth below, *Galderma* does not change the legal standard for proving obviousness, thus any one of these failings alone is sufficient to defeat Defendants' obviousness argument.

A. Defendants Failed to Establish a Recognized Problem to Be Solved

Galderma confirmed that an obviousness analysis must begin with the identification of a recognized problem to be solved in the prior art. Specifically, in *Galderma*, the Federal Circuit found that such a problem existed in the art in the form of a need for retinoid acne treatments to be available in multiple concentration strengths. 737 F.3d at 736-737. In contrast, here, the prior art provides no support for Defendants' two alleged "problems." Defendants alternately argued that "treatment of PBA" or safety concerns with the 60/150 mg/day DM/Q dose were the problems to be solved. D.I. 444 at 3-4. Both sides' experts agreed, however, that at the time of the invention, PBA had already been safely and effectively treated by the existing 60/150 DM/Q dose. *See, e.g.*, D.I. 432 at 7-8; D.I. 446 at 16, 25; D.I. 449 at 2, 8-9. Moreover, the prior art itself recognized the 60/150 mg/day DM/Q dose as safe despite explicitly considering the alleged safety concerns cited by Defendants. D.I. 446 at 20-23. Thus, Defendants' alleged problems did not exist at the time of invention. Accordingly, under *Galderma,* Defendants' failure to establish the existence of a problem to be solved remains fatal to their obviousness case.

B. Defendants Failed to Prove That There Was a Motivation to Select the Claimed DM and Q Doses and Claimed Weight Ratios for Treatment of PBA

Galderma confirmed that obviousness requires a motivation to arrive at the claimed invention. 737 F.3d at 737-38 ("the dispute is whether there was a motivation to select the claimed 0.3% adapalene composition in the disclosed range.") In *Galderma*, the Federal Circuit found "motivation to select a 0.3% adapalene composition for the treatment of acne" because 0.3% was disclosed in the prior art's preferred range of adapalene concentrations for the treatment of acne. *Id.* at 737-38. Additionally, the Federal Circuit cited four studies showing the exact same 0.3% composition was well tolerated in patients, and one study concluding that the 0.3% composition was "***particularly suitable*** for the treatment of acne." *See id.* at 737 (emphasis added).

No such fact pattern exists here. Instead, here, the prior art does not disclose the use of the claimed DM/Q doses for PBA at all, let alone disclose those doses or weight ratios as "preferred" or "particularly suitable" for the treatment of PBA. *See, e.g.*, D.I. 446 at 5-13.[2] Nor have Defendants shown that the specific dose of 40 mg/day DM and of 20 mg/day Q in claims 15 and 17 of the '484

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[2] Indeed, Defendants do not dispute that at least the claimed doses of Q are not disclosed for the treatment of PBA in any prior art. *See, e.g.*, D.I. 429 at 1 (arguing that the prior art "teaches every aspect of [the claimed] subject matter ***except*** for the claimed lower dose ranges for Q") (emphasis added); D.I. 444 at 3 (acknowledging "the use of a higher dose of Q" in the prior art compared to the claimed inventions).

patent existed in the prior art for the treatment of PBA. *See, e.g.,* D.I. 446 at 11-14. Accordingly, *Galderma* does not remedy Defendants' failure of proof on motivation, which remains fatal to their obviousness case. *See* D.I. 432 a 7-9; D.I. 446 at 5-10, 23-24, 32-37; D.I. 449 at 2-5.

C. Defendants Failed to Prove that a POSA Would Have Reasonably Expected the Claimed Doses of DM With the Claimed Doses of Q in the Claimed Ratios Would Be Successful in Treating PBA

While *Galderma* did not specifically use the words "reasonable expectation of success," it can be inferred from the Federal Circuit's reasoning on motivation. As set forth above, the Federal Circuit found that the prior art in *Galderma* disclosed the claimed 0.3% composition to be within the preferred range of concentrations that were known to treat the claimed condition, acne, 737 F.3d at 735, and further disclosed that the claimed 0.3% composition was "***particularly suitable*** for the treatment of acne." *Id.* at 737 (emphasis added). As also set forth above, here, the prior art discloses neither the use of the claimed DM/Q doses to treat PBA, nor that such doses were "preferred" or "particularly suitable" for the treatment of PBA. Instead, Defendants' experts—who have no experience treating PBA or developing PBA treatments—based their expectation of success opinions entirely on a case report of a single patient who was administered 60/150 mg/day DM/Q—well ***above*** the claimed DM/Q doses. D.I. 429 at 11-17; D.I. 450 at 3-5, 15-16.[3] Defendants put forth ***no*** prior art evidence of how, if at all, the much lower, claimed DM/Q doses, in the claimed ratios, would have been expected to affect that patient's PBA. D.I. 446 at 6, 33.

Thus, *Galderma* does not affect Defendants' failure to prove that a POSA in 2002 would have had a reasonable expectation that the claimed DM/Q doses, in the claimed ratios, would have been successful in treating PBA. *See* D.I. 432 at 10-13; D.I. 446 at 30-37; D.I. 449 at 11-12. Defendants' failure to prove a reasonable expectation of success remains an independent ground upon which their obviousness case fails.

D. Secondary Considerations of Non-Obviousness

Galderma also does not change the legal standards for secondary considerations of non-obviousness set forth in Plaintiffs' post-trial briefing. *See* D.I. 432 at 11-16; D.I. 446 at 26-29, 32-36; D.I. 449 at 5-6, 13-17.

II. CONCLUSION

As set forth above, the Federal Circuit's decision in *Galderma* further supports the nonobviousness of the claimed inventions of the '282 and '484 patents. *See also* D.I. 431, 432, 446, 447 and 449.

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[3] That case report also failed to establish a cause and effect relationship, and was inconsistent with other, more reliable prior art, including the double-blind, placebo controlled study reported in the Smith Abstract. D.I. 446 at 7-8.

Respectfully,

/s/ Maryellen Noreika

Maryellen Noreika (#3208)

MN/dlw
cc: Clerk of Court (Via Hand Delivery)
All Counsel of Record (Via Electronic Mail)